Results: Based on the findings of the standardized preoperative questionnaire, patient centered outcomes for success were defined as (1) maintenance of living independence, (2) maintenance of ambulatory status, (3) control/relief of pain, (4) no additional/nonroutine physician visits, and (5) survival for 1 year. While overall success for maintenance of independence was 89% (n = 849), maintenance of ambulation 84% (n = 802), control/relief of pain 48% (n = 461), no additional physician visits 36% (n = 340), and 1-year survival 79% (n = 755), overall patient centered success (achievement of all five parameters) was accomplished in only 23% (n = 218) of patients. Of 20 variables examined, only end-stage renal disease (odds ratio [95% confidence interval, 2.21 [1.26-3.88]; $P = .006$) and impaired ambulatory status preoperatively (odds ratio [95% confidence interval 1.76 [1.12-2.79]; $P = .015$) were independent predictors of failure using bivariate and multivariate analysis. Type of intervention (open vs endo) was not a predictor of outcome. The probability of failing to achieve patient centered success was 88% in patients with end-stage renal disease, 83% in patients with impaired ambulatory status preoperatively, and 93% in patients with both (representing 30% of the entire patient cohort). The probability of failure was still 73% even when neither predictor was present.

Conclusions: When allowing patients to define successful outcome after intervention for CLI, success was achieved in fewer than 25% of cases. Patients with end-stage renal disease and impaired ambulatory status rarely achieved success. These data reiterate that CLI is associated with declining overall health undeterred by vascular intervention and question whether intervention is an appropriate use of healthcare resources in various high risk cohorts.

Radiation Skin Injury: More Frequent After Complex Endovascular Procedures?

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Objectives: The risk of deterministic skin injury is determined by the dose of ionizing radiation in any given procedure. Transient erythema occurs at doses of 2-5 Gy, while permanent epilation, ulceration, and desquamation are expected at doses above this level. Complex endovascular procedures (CEP) such as fenestrated endovascular aortic stent grafts (FEVAR) are associated with high radiation doses. Although CEP cases are being performed with increasing frequency, the risk of associated skin injury has not been examined. We hypothesized that skin injury following these exposures is likely under recognized and under reported. This study examined the frequency and severity of deterministic effects and evaluated patient characteristics that might predispose to radiation injury in CEP

Methods: CEP was defined as a procedure with a radiation dose ≥Gy (NCRP threshold for substantial radiation dose level [SRDL]). Radiation dose and operating factors were recorded for all CEP performed in a hybrid room over a 30-month period. Patient medical records were retrospectively reviewed for evidence of skin injury. Patients were seen in follow-up daily until discharge and then at weeks 2, 6, months 3, 6, and 1 year. Phone interviews were conducted to determine the presence of any skin related complaints, including erythema, epilation, and necrosis. Peak skin dose (PSD) distributions were calculated for FEVARs using custom software employing input data from fluoroscopic machine logs. These calculations were validated against gafchromic film measurements. The effects of patient factors and procedural skin dose on cutaneous skin injury were analyzed for statistical significance. Dose was summed for the subset of patients with multiple procedures within 6 months of the SRDL event, consistent with Joint Commission recommendations.

Results: 61 CEP reached a RAK of 5 Gy. There were 50 FEVARs, 6 embolizations, 1 TEVAR, 1 EVAR, 1 carotid, and 2 visceral interventions. The patient cohort was 79% male and had a mean body mass index of 31. The average RAK was 8 ± 2 Gy (5.0-5.9 Gy). 16 patients had multiple CEPs within 6 months of the SRDL event, with a mean cumulative RAK of 12 ± 3 Gy (7.0-18.4 Gy) for this patient subset. The mean FEVAR PSD was 6.8 ± 3.4 Gy (3.7-17.8 Gy), with a mean PSD/RAK ratio of 0.67 ± 0.12. Three patients were lost to follow-up before their first postoperative visit. Patients were seen at 2 weeks (95%), 6 weeks (88%), 3 months (84%), 6 months (73%), and 1 year (79%) following the SRDL event. No radiation skin injuries were found. Two patients had skin complaints unrelated to radiation, an HSV culture positive focal outbreak of shingles 2 weeks following the procedure and a diffuse desquamating, erythematous drug reaction.

Conclusions: Radiation doses in this study exceeded published thresholds for cutaneous injury; yet, no radiation skin injuries were observed. This data suggests that other variables besides radiation dose may play a role in deterministic injuries. Nonetheless, deterministic skin injuries may be less frequent than previously reported, and the risk is not increased in complex endovascular procedures.

"Off-the-Shelf" Devices for Complex Aortic Aneurysm Repair

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Objectives: Fenestrated devices currently require a 3- to 4-week manufacturing period prior to implantation; as such, there have been efforts to develop "off-the-shelf" (OTS) devices to reduce the time before definitive treatment can be accomplished. Initial estimates predicted that 60%-70% of patients might be amenable to this approach. We examined all patients treated for complex aortic problems at our institution during the past 12 months to evaluate the suitability and early outcomes of the OTS devices vs commercially available endovascular options.

Methods: Between July 2012 and July 2013, patients undergoing aortic aneurysm repair were extracted from a prospectively managed aortic database. Two OTS devices, the Cook p-branch and the Endologix Ventana device, were available thru clinical trials during this time frame. The custom Cook Zenith Fenestrated device (ZFEN) was also available and Food and Drug Administration approved during the study period. Patient demographics and suitability for repair with an OTS device were determined based on anatomic criteria.

Results: Out of 178 aortic aneurysms treated at our institution during this time period, there were a total of 94 patients with thoracoabdominal aortic aneurysm (II-IV) including pararenal (suprarenal and juxtarenal) aneurysms. Only 22 (23%) patients met anatomic criteria for OTS devices with 16 patients having these investigational devices implanted. The major exclusion criterion for the p-Branch device was renal artery location (axial and circumferential) while the limiting factor for the Ventana device was infra-SMA neck length restrictions. Four of the patients who would have fit criteria for an OTS device choose to have an Food and Drug Administration approved (ZFEN) device implanted instead and two patients opted for open repair as a result of follow-up requirements. An additional 17 patients received custom designed (ZFEN) devices (n = 21, 22%), whereas 57 (61%) others did not meet criteria for any available endovascular device and were repaired using alternative management strategies. The mean age and maximal aortic diameter of the two cohorts (OTS: ZFEN) was 71.8: 72.0 years (P = NS) and 61.3: 58.0 mm (P = NS), respectively. Technical success was 100%, with an overall 30-day mortality of 2.7% (n = 1, ZFEN). Major complications occurred in four patients (11%: OTS-1, ZFEN-3) and included renal dissection-1, superior mesenteric artery dissection-1, perinephric hematoma-1, and contrast-induced nephropathy-1.

Conclusions: Pararenal aneurysms comprise the minority of patients presenting for repair to a complex aortic referral center. While OTS device strategies will reduce the waiting times for patients with complex aortic aneurysmal disease, a significant number will still require custom made devices or other repairs until additional device designs become available. Early experience with OTS devices does not demonstrate any significant renal risks, however, the treatment numbers are low and should be interpreted with caution until larger confirmatory studies are published. Further studies comparing the outcomes of these techniques are required to establish the best approach to handle endovascular repair of complex aortic aneurysms.

The Utility of the ABI Value as a Screening Test for Disseminated Atherosclerosis

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Objectives: Cardiovascular disease is the leading cause of death in the United States; nevertheless, there are no optimal or universally accepted screening tests for disseminated atherosclerosis. Patients with peripheral artery disease (PAD) are at increased risk for having atherosclerosis in additional vascular territories. The goal of this study was to determine the utility of the ankle brachial index (ABI) value to predict coronary artery disease (CAD), cerebrovascular disease (CVD), and carotid artery stenosis (CAS).

Methods: A database of 3,561,679 subjects who underwent vascular screening was used. PAD was defined as an ABI ≤ 0.9. CAS was diagnosed if either artery demonstrated ≥50% stenosis. CVD and CAD history was obtained from subject questionnaires. Correlation of decreasing ABI values with vascular disease in other territories was performed.

Results: PAD was present in 125,889 subjects (3.5%). PAD subjects were more likely to be >70 years (55.1% vs 25.9%), male (66.2% vs 62.2%), to have a smoking history (59.7% vs 43%), hypertension (62.1% vs 43.9%), diabetes (20.2% vs 9.6%), and hypercholesterolemia (56.1% vs

50.4%) than non-PAD subjects ($P < .001$). PAD subjects were more likely to have CAS (17.5% vs 3.4%), prior strokes (5.4% vs 1.6%), prior transient ischemic attack (8.1% vs 3.2%), prior myocardial infarction (10.3% vs 3.6%), and prior coronary revascularization (14.8% vs 4.9%) than non-PAD subjects ($P < .001$). There was a statistically significant correlation between decreasing ABI value and an increased prevalence of CAS, CAD, and CVD ($P < .001$) (Fig). For example, patients with an ABI between 0.41 and 0.60 had a 26.4% incidence of CAS, which increased to 34.9% for those with an ABI ≤ 0.4. Even patients with a minimally decreased ABI (0.81-0.9) had significantly increased rates of vascular disease in other territories compared with patients with normal ABIs.

Conclusions: The ABI value is directly and significantly associated with the prevalence of CAS, and with a history of CAD and CVD complications. These data support the use of the ABI as a noninvasive, inexpensive, easily reproducible screening test that can reliably identify patients at increased risk for cerebrovascular and cardiovascular complications.

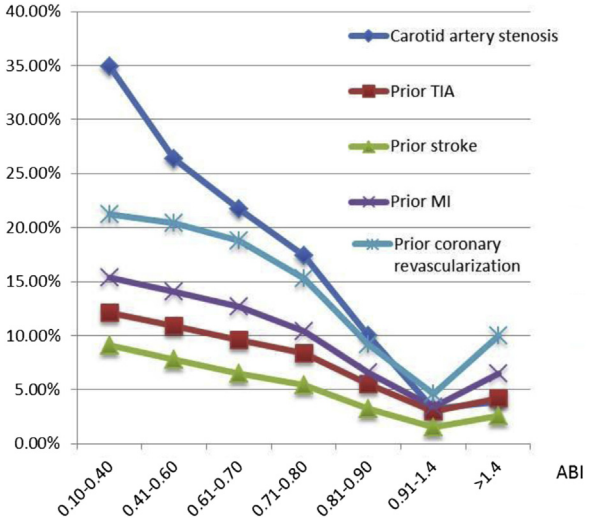

Fig.

A Systems Based Analysis of p27kip1 as the Driver for Pathologic Vein Graft Remodeling

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Objectives: The factors that lead to vein graft bypass restenosis and ultimate clinical failure are incompletely understood. Cell cycle regulators, such as the cyclin-dependent kinase inhibitor $p27^{kip1}$, have been shown to play critical roles in the regulation of vascular cell proliferation. Conte et al and van Tiel et al, in fact, have identified a single nucleotide polymorphism (SNP) in the promoter region of the $p27^{kip1}$ gene that is associated with divergent clinical outcomes following lower extremity vein bypass grafting and coronary artery stenting, respectively. Both clinical studies demonstrated the $p27^{kip1}$-838C>A SNP to be associated with significantly increased rates of clinical success compared with the -838CC and -838CA genotypes. Although these represent highly significant and clinically relevant findings, these studies are primarily associative in nature and provide limited insight into the mechanistic details. Here we aim to develop a model to explore the precise mechanisms through which $p27^{kip1}$ influences the local vascular wall biology. There is a long history of divergent phenotypes of vein graft remodeling secondary to alterations in flow and wall shear stress. Previous work in our laboratory using a novel vein graft model demonstrated increased outward remodeling and decreased neointimal hyperplasia in response to high-shear environments. Using high-throughput genomics, we examined the specific genes and pathways that are closely associated with $p27^{kip1}$ and demonstrate differential expression in the divergent clinical phenotypes seen in alternate flow and shear stress conditions.

Methods: A rabbit carotid artery interposition graft with jugular vein was placed and differential flow states were created through outflow branch ligation. Graft diameters and flow rates were documented at the time of implantation and harvest with ultrasound imaging. Vein grafts were harvested at 2 hours, 1 day, 7 days, and 28 days following implantation. Whole vessel homogenates were analyzed for gene expression using a custom Agilent rabbit microarray. Next, ingenuity pathway analysis (IPA) (Ingenuity, Redwood City, Calif) was employed to generate a list of the closest 150 upstream and downstream genes in relation to $p27^{kip1}$. This list was cross-referenced to the rabbit array list to identify overlapping genes, and this set of $p27^{kip1}$-associated genes was analyzed for divergent expression profiles between high and low shear conditions. These genes were then further explored using IPA for ontologic analysis and creation of signaling networks. dChip software (Harvard, Boston, Mass) was used for clustering analysis and heat map generation.

Results: Outflow branch ligation resulted in an immediate 90% reduction in flow on the ligated (low-flow) vein graft side compared with the high flow side (3.1 ± 0.4 vs 30.0 ± 2.2 mL/min), and a 15-fold difference in mean flow rates was observed throughout the 28-day perfusion period ($P < .001$). The reduction in flow led to a robust hyperplastic response, so that by 28 days a sevenfold increase in neointimal thickness was noted in the low-flow vs the high-flow vein grafts (231 ± 35 vs 36 ± 18 μm;

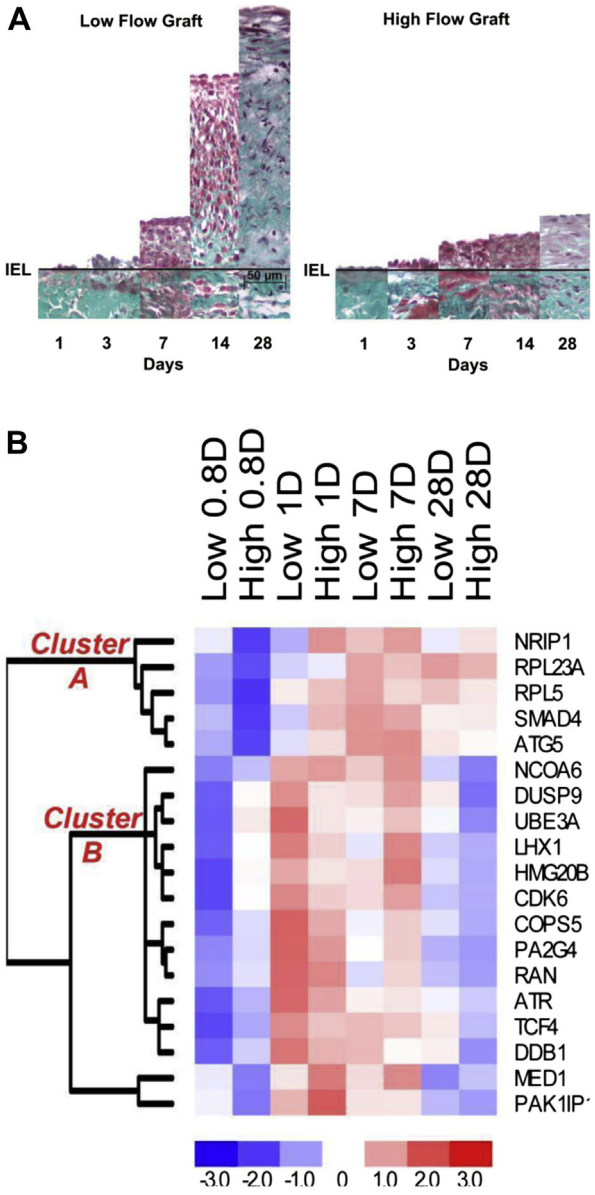

Fig 1.